Hepatitis C Treatment in the Primary Care Setting: Increasing Access to Curative Therapies

Amber Slevin, PharmD, BCACP, CTTS
Clinical Pharmacist & Assistant Professor of Practice
Family HealthCare & North Dakota State University School of Pharmacy
Fargo, ND

LEARNING OBJECTIVES

- Describe basis for Hepatitis C Virus (HCV) management shift to primary care and other community clinics
- Outline a clinical model for providing primary care based HCV treatment
- Summarize HCV treatment barriers with a focus on issues specific to rural and underserved populations
- Outline resources to support providers treating HCV

DISCLOSURES

- I have no conflicts of interest to report, financial or otherwise.

HCV BACKGROUND

- HCV is a bloodborne pathogen that infects the liver

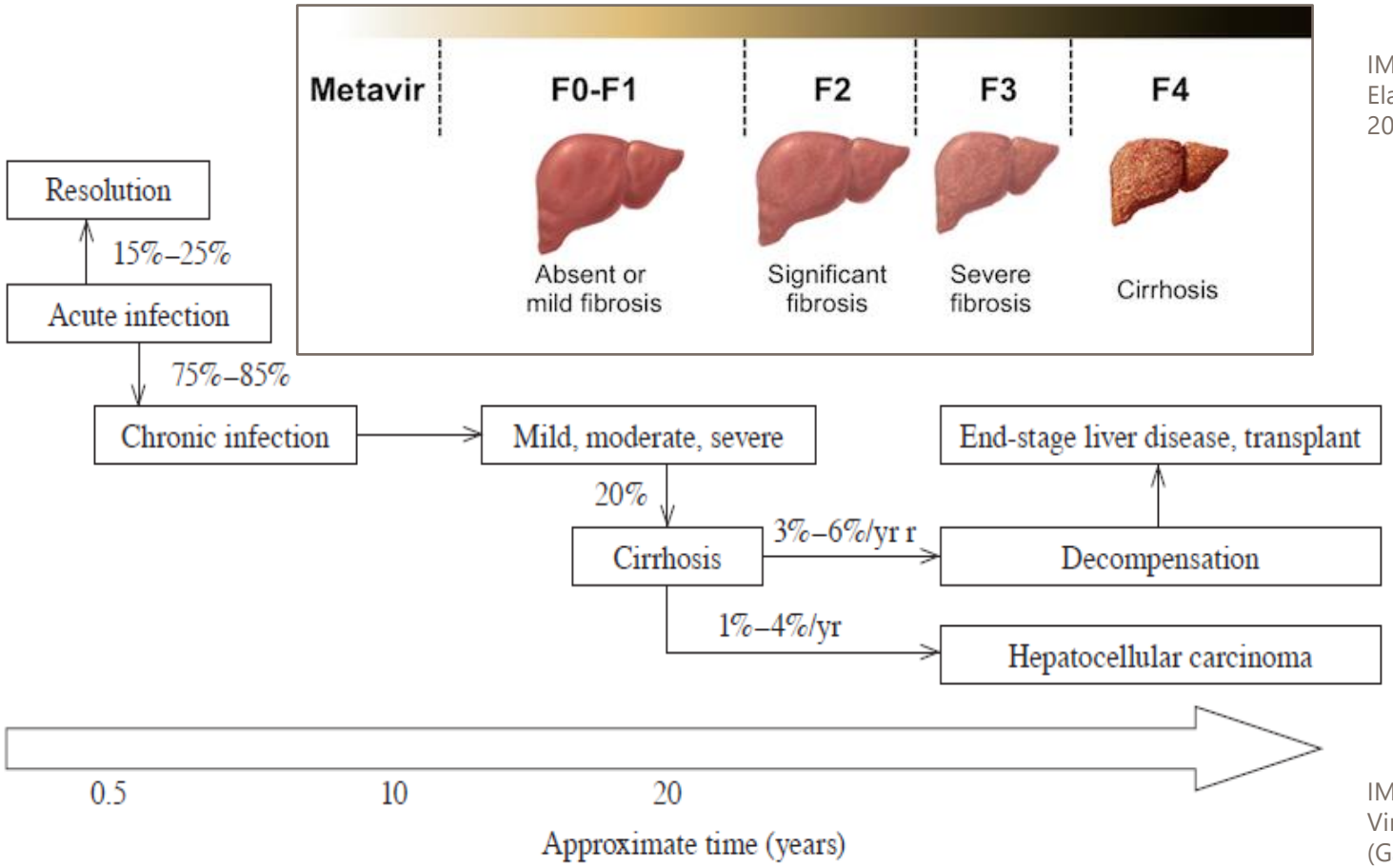


IMAGE SOURCE: Castera Transient Elastography Breakpoints, Hepatitis C Online, 2021.

IMAGE SOURCE: Progression of Hepatitis C Virus, American College of Clinical Pharmacy (Gastrointestinal Disorders), 2016

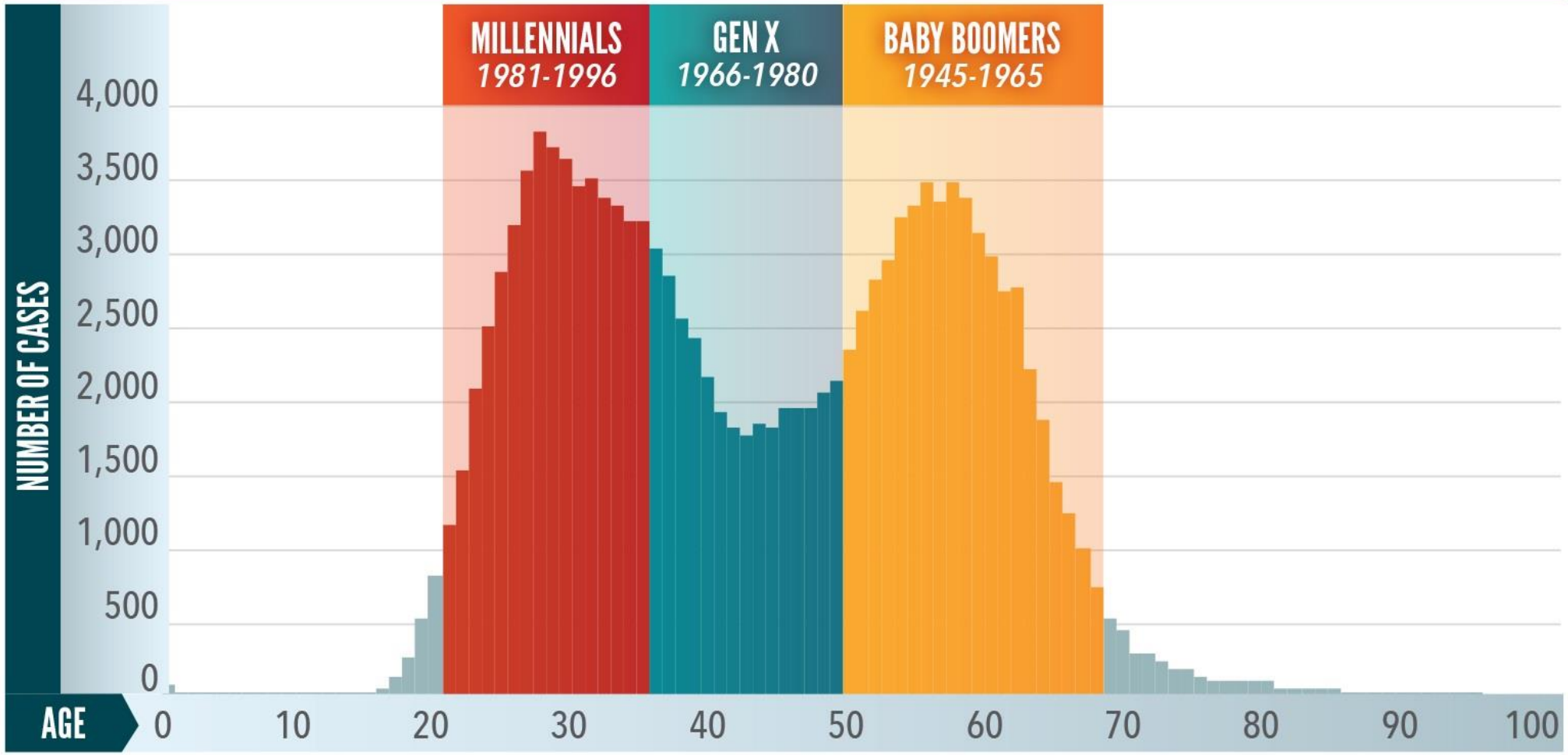
HCV BACKGROUND[1,2]

The most common cause of HCV transmission currently is sharing needles or other equipment associated with injection drug use.

Other transmission routes:

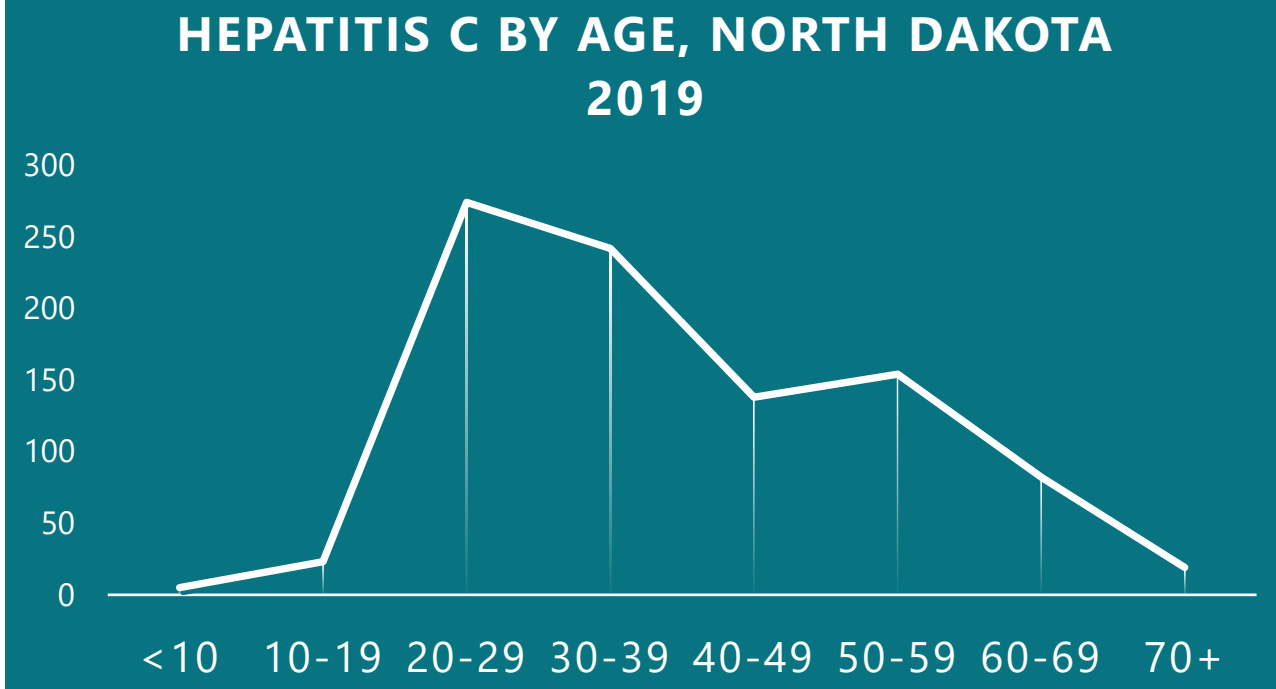
https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#b1

New Reports of Chronic Hepatitis C High in Multiple Generations



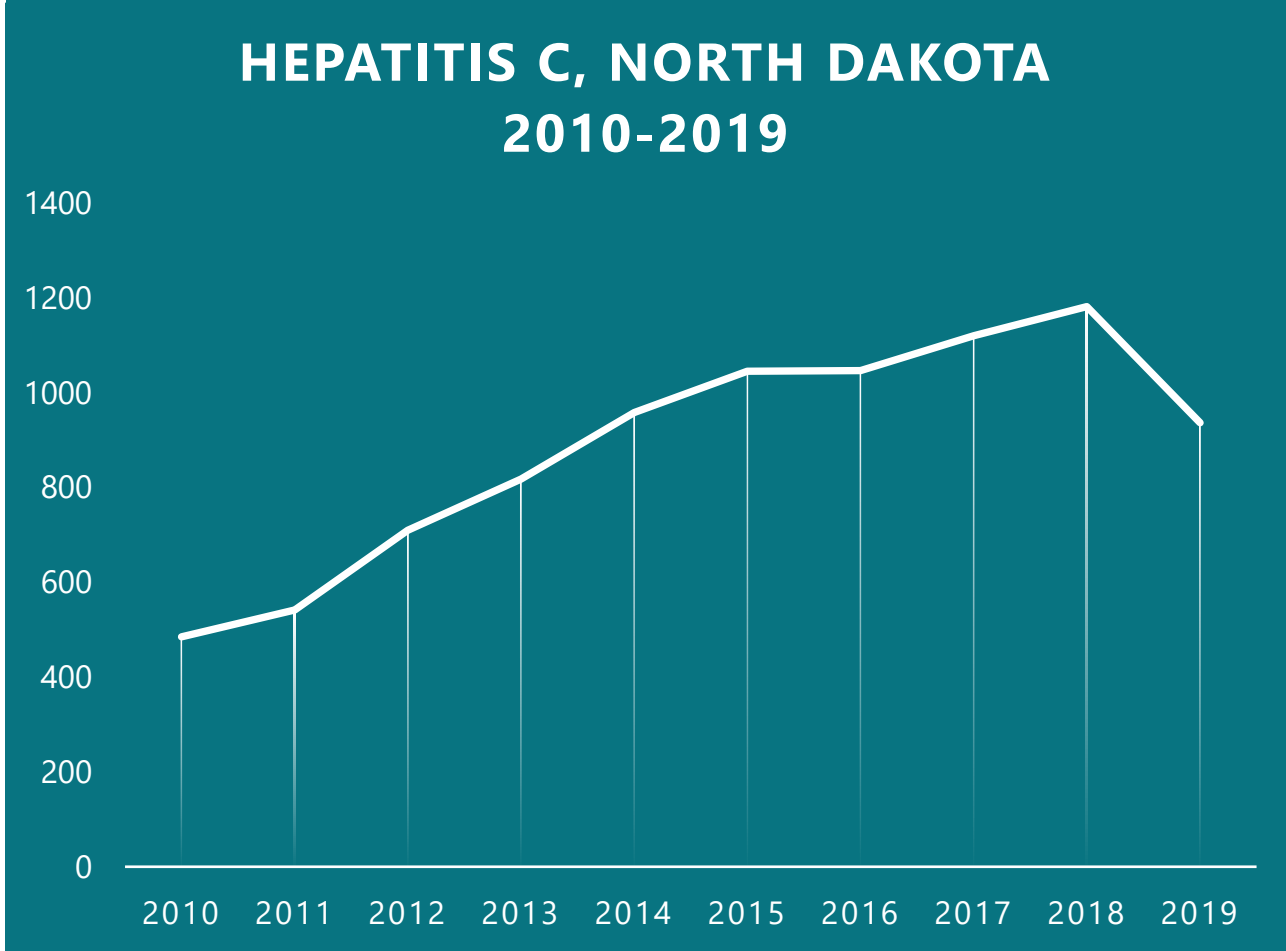
SOURCE: National Notifiable Diseases Surveillance System, 2018

The millennial generation has passed the baby boomer generation in Hepatitis C case numbers



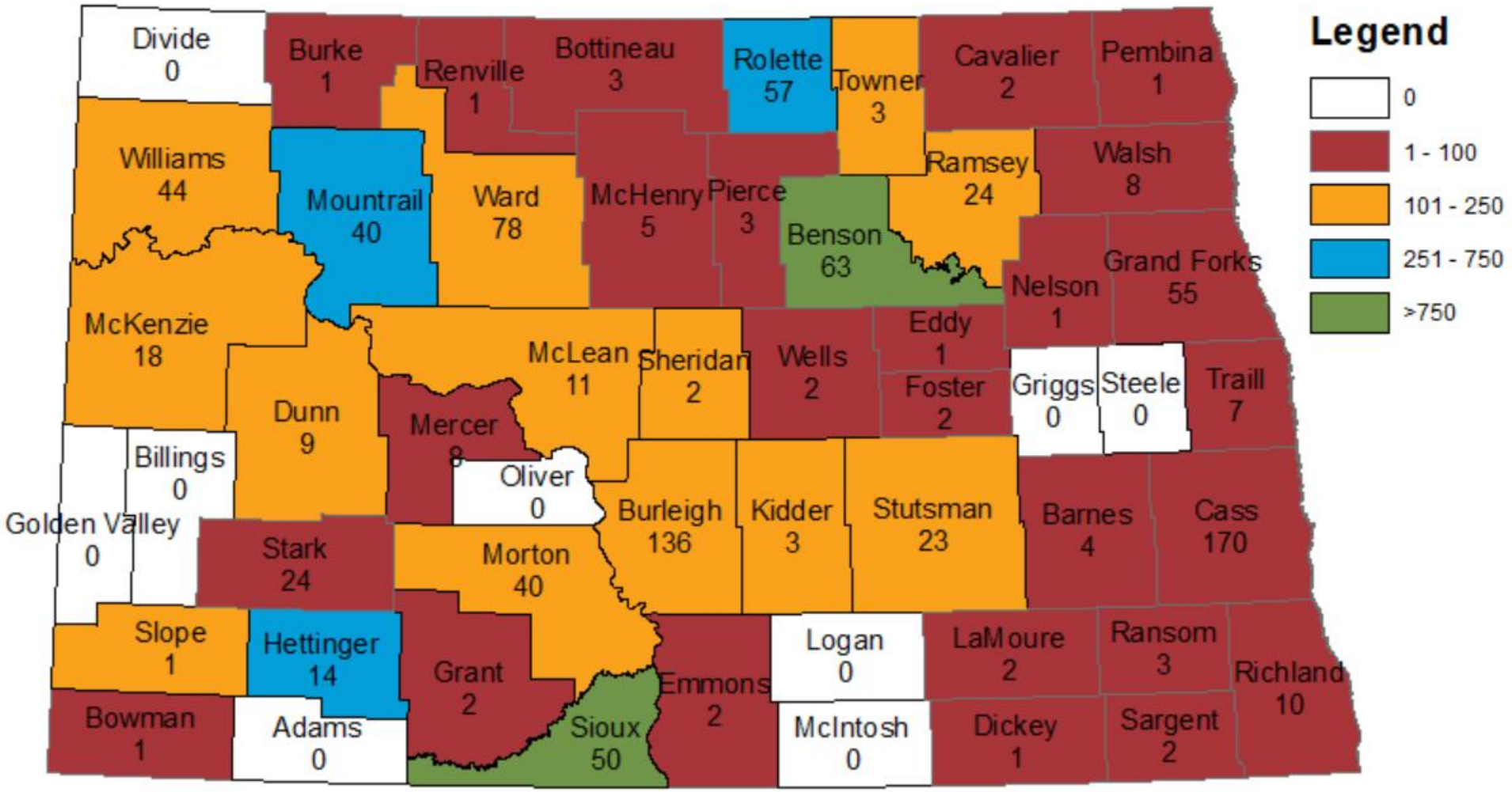
Source: North Dakota Department of Health, Division of Sexually Transmitted & Bloodborne Diseases

Hepatitis C infections more than doubled in the past decade in North Dakota



Source: North Dakota Department of Health, Division of Sexually Transmitted & Bloodborne Diseases

HEPATITIS C COUNT AND RATE*, 2019



***Per 100,000 people.** SOURCE: North Dakota Department of Health, Division of Sexually Transmitted & Bloodborne Diseases

New HCV screening recommendations in 2020[3]

SOURCE: CDC Recommendations for Hepatitis C Screening, *MMWR*, April 2020

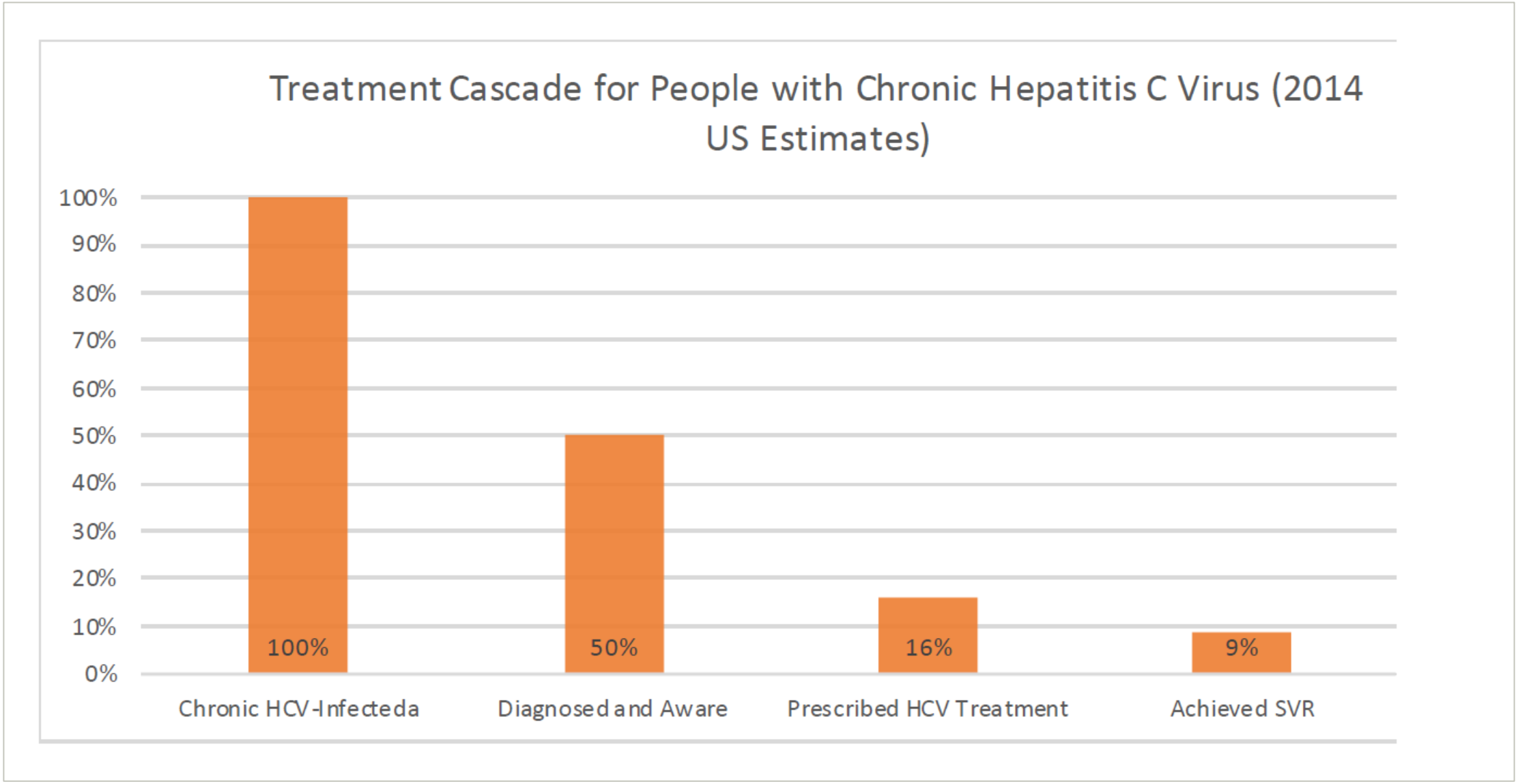


Image adapted from: Yehia BR, Schranz AJ, Umscheid CA, Lo Re V. The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis. Rizza SA, ed. *PLoS ONE*. 2014;9(7):e101554. doi:10.1371/journal.pone.0101554

HCV TREATMENT:

CALL FOR A SHIFT TO PRIMARY CARE

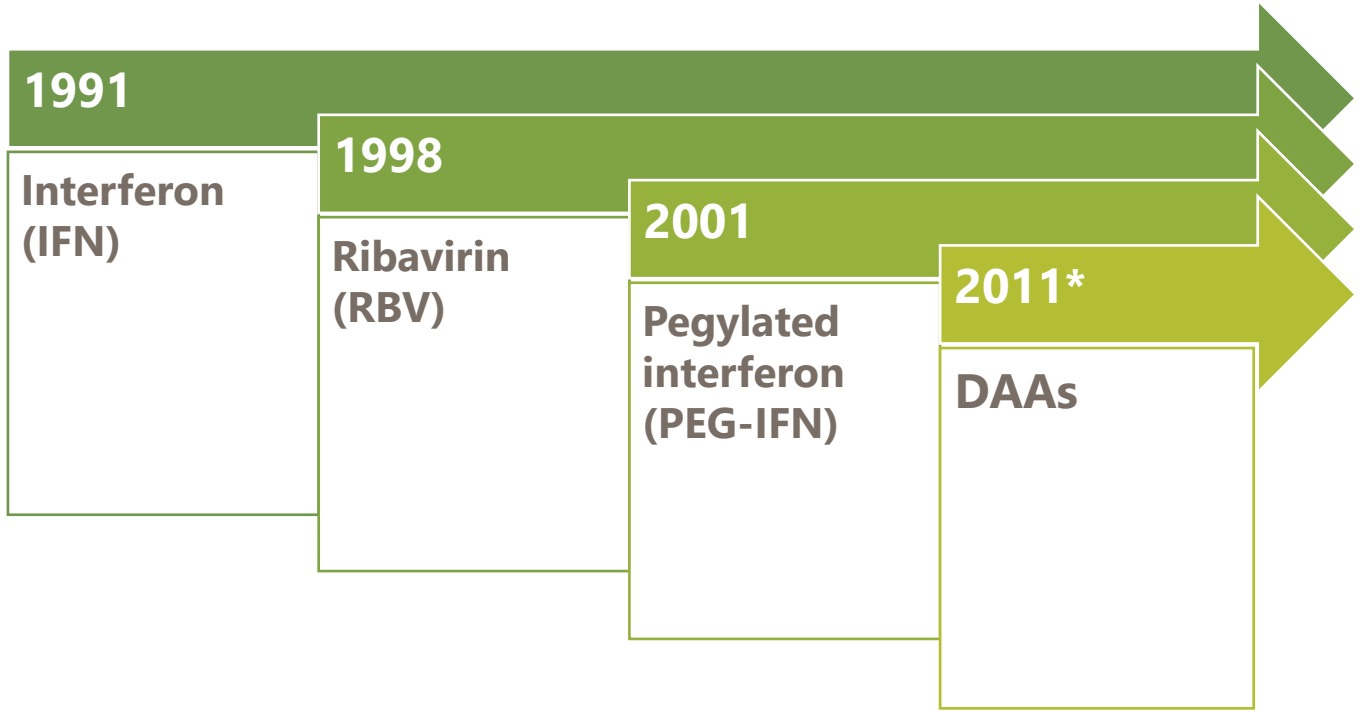
"To accomplish the goal of HCV eradication, we will need to markedly expand our pool of providers to PCP [primary care providers] and NPs. Data suggest that they can effectively treat most patients with HCV."

Tram T Tran, MD[6]

Clin Liver Dis. 2018 Mar; 11(3): 66–68.

HCV TREATMENT: CALL FOR A SHIFT TO PRIMARY CARE

- "New" Hepatitis C Direct Acting Antiviral (DAA) therapy is simple, safe/well tolerated, and highly effective



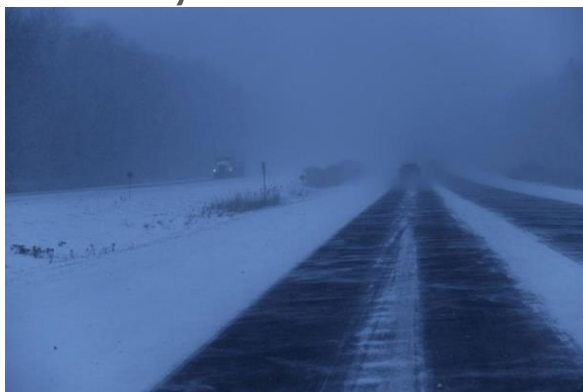
*Use of/need for ribavirin along with DAAs has significantly decreased since new DAAs approved in 2014

HCV TREATMENT: CALL FOR A SHIFT TO PRIMARY CARE

- Hepatitis C DAA highlights
  - >95% chance of Sustained Virologic Response 12 weeks after treatment (SVR12; cure)[7]
  - Common side effects are manageable, severe risks are extremely rare
  - Specialist involvement only needed in complicated cases (severely advanced liver disease, co-infection with HBV or HIV, post-transplant)

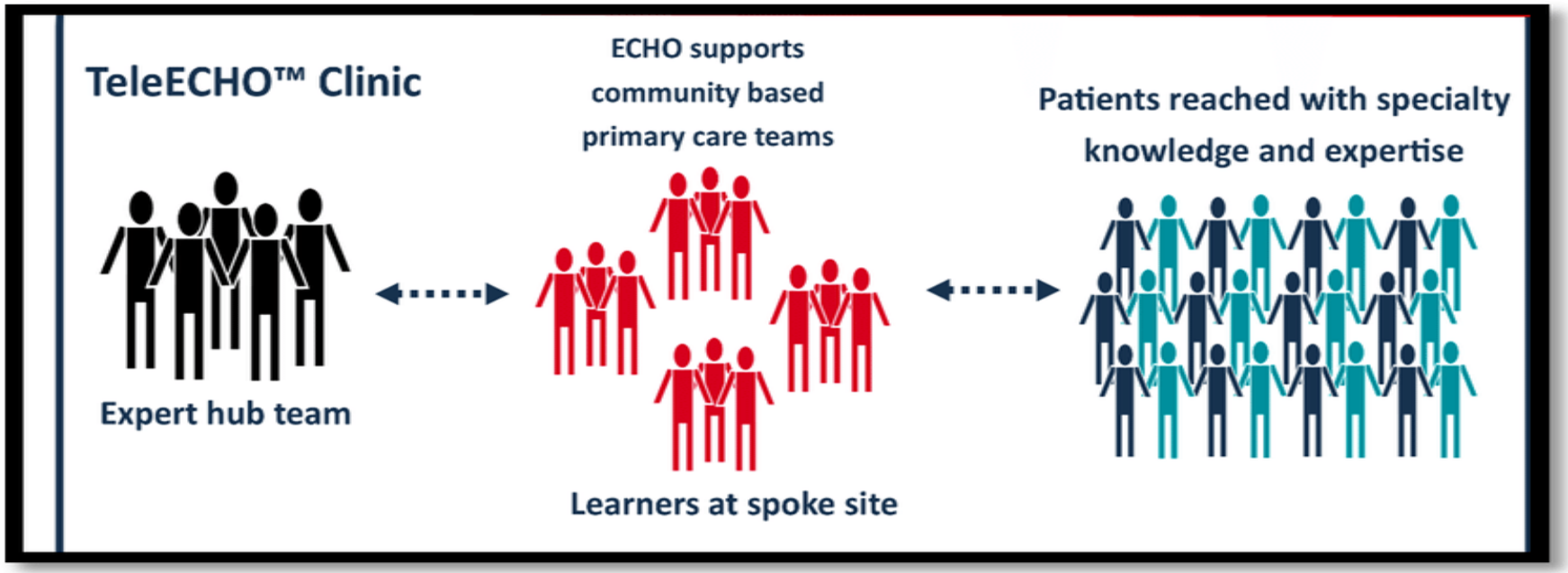
HCV TREATMENT:
CALL FOR A SHIFT TO PRIMARY CARE

- Liver disease staging now simplified; biopsy not necessary
  - Staging modality can be as simple as lab work which may require further diagnostic work (elastography/ultrasound)
- Reduce risk of being lost to specialist referral follow-up, especially when patient have barriers (location, cost, etc)



HCV TREATMENT:
CALL FOR A SHIFT TO PRIMARY CARE

- Increase in supportive resources available to general practitioners, including ECHO Model (Extension for the Community HealthCare Outcomes)



ECHO model of care (reproduced from ECHO Institute, UNM, USA).

HCV TREATMENT:
CALL FOR A SHIFT TO PRIMARY CARE

- Data indicates equitable treatment outcomes in primary/community-based settings as compared to specialist settings
  - Evidence for nurse practitioner, physician assistant, and pharmacist-run clinics[8,9,10]

Transition Pause

What questions do you have?

PRIMARY CARE HCV TREATMENT MODEL EXAMPLE:

FAMILY HEALTH CARE (FHC)

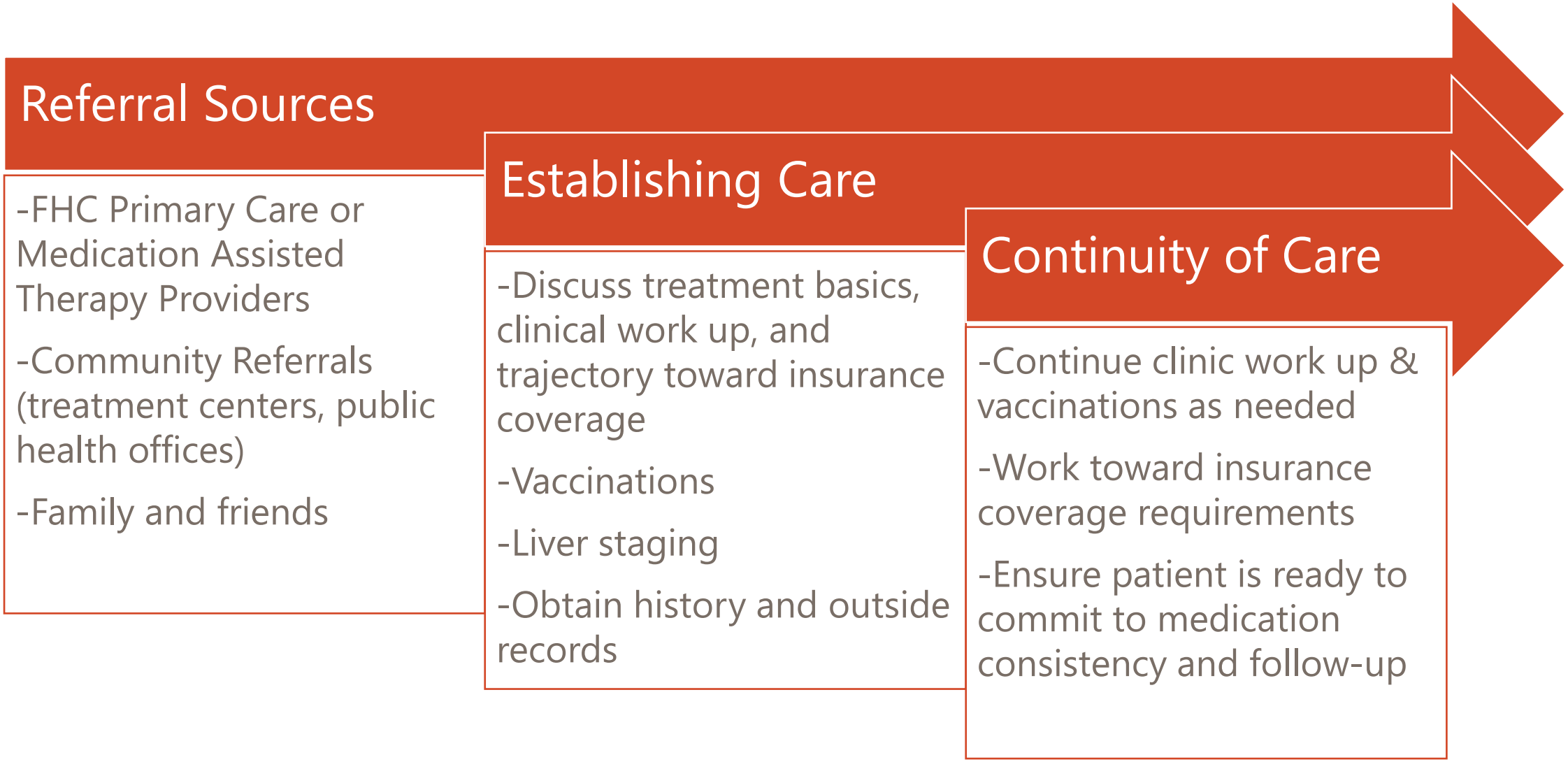
The HCV Team

- Kali Luecke, PA
- Kayla Nelson, NP
- Amber Slevin, PharmD
- NDSU Pharmacy Intern

Partnerships with nursing and in house pharmacy team.

Established October 2018.

PRIMARY CARE HCV TREATMENT MODEL EXAMPLE: FHC



PRIMARY CARE HCV TREATMENT MODEL EXAMPLE: FHC

Prior Authorization (PA)

-Required by most insurance providers

-Best if criteria are known early on in the patients care

-Variations in preferred product, sobriety requirements, etc between insurance companies

Treatment Initiation

-In depth, pharmacy-delivered medication education (adherence, side effects, etc)

-Comprehensive medication reconciliation & drug-drug interaction review

-Coordinate follow-up

During Treatment

-Regular phone check in from pharmacy intern (or other care coordinator)

-1-2 provider visits (some practices do not require); flexible

-Coordination of SVR12 follow-up

PRIMARY CARE HCV TREATMENT MODEL EXAMPLE: FHC

After Treatment

-Document treatment end date & final adherence assessment based on start date

-Education on re-infection prevention/harm reduction

-Ensure HCV RNA is undetectable 12 weeks after treatment completion (SVR12); document cure or pursue re-treatment

After SVR12

-No further follow-up or screening required for HCV unless ongoing reinfection risk factors (ie IVDU, screen annually with HCV RNA quant lab)

-Ensure those with advanced liver disease are connected with appropriate care

FAMILY HEALTHCARE HCV CLINIC OUTCOMES*

- Approximately 150 patients seen in HCV clinic
- 45 patients who have successfully completed treatment
- 6 patients currently on HCV treatment
- 30 patients with SVR12 (cure) confirmation
- 15 patients awaiting due date of SVR12 labs
- 1 patient lost to follow-up on treatment

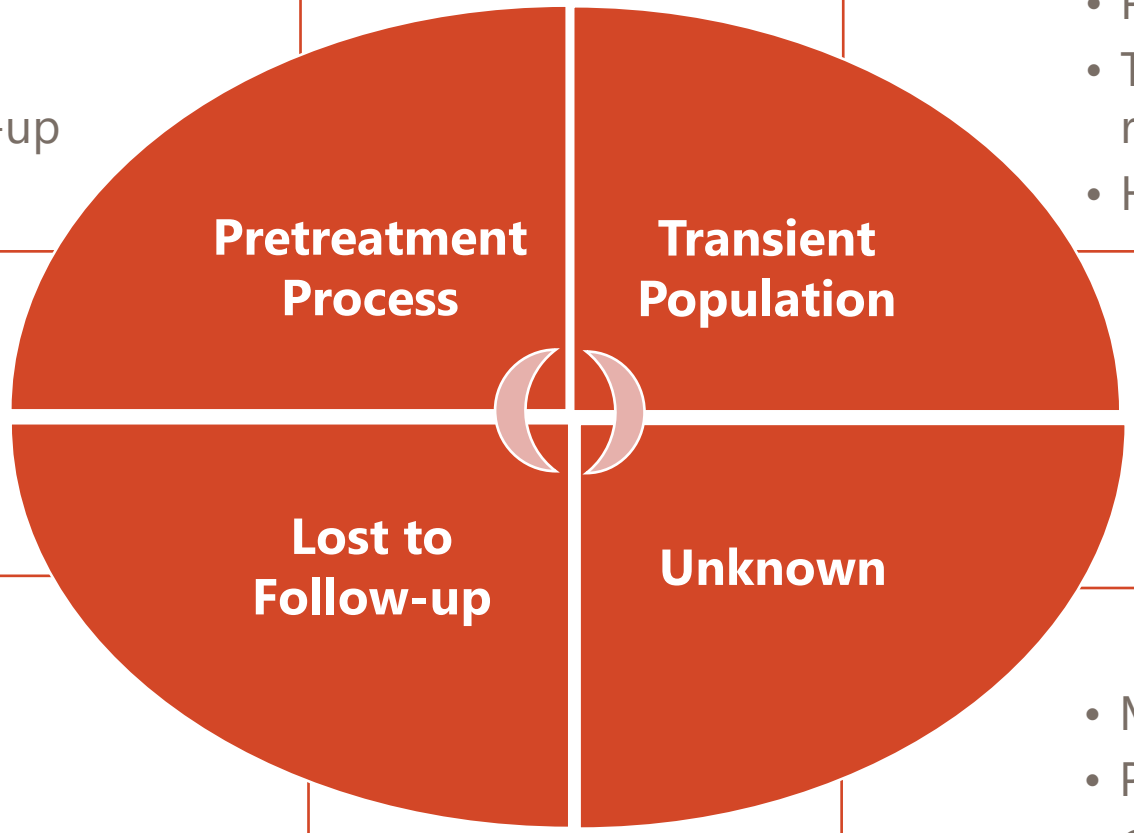
**Outcomes as of May 2021*

FAMILY HEALTHCARE OUTCOMES: BARRIERS

Why have 150 patients been seen but only 50 started on treatment? Our barriers:

- Insurance PA requirements
- Clinical work-up time frame?

- Post-corrections
- Treatment facility residents
- Homeless



- "No shows"
- Contact info changes

- Misconceptions?
- Provider change?
- Comorbidities?

GENERAL BARRIERS

- Expense of HCV medications (DAAs)
  - Approximately $15,000 per month (ie at least $30,000 per treatment course)

- Insurance Criteria/Paperwork
  - Can be burdensome to find, fulfill, and document all criteria, especially if criteria is not publically available

GENERAL BARRIERS

- Substance Use Disorder (SUD) Comorbidities
  - Insurance restrictions (improving)
    - Need to move toward “treatment as prevention”
  - Connection to resources for SUD/reinfection risk (harm reduction, treatment programs)

- Access to HCV care
  - Previously specialist treated disease state (ND Medicaid and many other payers have dropped specialist prescriber agreement)
  - Socioeconomic and rural disparities
  - **No known HCV treating providers west of Minot & Mandan**

INTERESTED IN PROVIDING PRIMARY CARE-BASED HCV TREATMENT?

Essential Roles

- Provider prescriber(s)
  - Evidence for nurse practitioner, physician assistant, and pharmacist-run clinics
- Care coordination (nurse, social worker, pharmacist)
- Pharmacy partnership (internal, external, or both)
  - “Go to” specialty pharmacy or local pharmacy depending on dominant payer mix and institution

INTERESTED IN PROVIDING PRIMARY CARE-BASED HCV TREATMENT?

Helpful Clinical Resources

- Clinical guidelines
  - AASLD/IDSA HCV Guidance- Recommendations for Testing, Managing, and Treating Hepatitis C: https://www.hcvguidelines.org/
- General educational resource
  - Hepatitis C Online: https://www.hepatitisc.uw.edu/
- Drug-drug interaction site
  - Liverpool® HEP Drug Interaction Checker: https://www.hep-druginteractions.org/checker

INTERESTED IN PROVIDING PRIMARY CARE-BASED HCV TREATMENT?

ND Medicaid HCV Treatment Coverage Criteria & Forms

- Criteria: http://www.hidesigns.com/ndmedicaid/pdl/2021.html
- Forms: http://www.hidesigns.com/ndmedicaid/pa-forms.html
- Note: criteria updated July 1, 2021 to significantly reduce sobriety/lab requirements for patients that:
  - 1) do not have a history of SUD
  - 2) have a history of a SUD but it is either remote or the patient is/has recently been in SUD treatment

INTERESTED IN PROVIDING PRIMARY CARE-BASED HCV TREATMENT?

"Human" Resources

- Project ECHO: https://www.hennepinhealthcare.org/project-echo/
- North Dakota Dept of Health: HIV/STI/Viral Hepatitis Department
  - Contact information at end of slide deck
- Other HCV treatment teams
  - Family HealthCare: amber.slevin@ndsu.edu

SUMMARY

- There is much work to be done across the HCV Care Cascade (diagnosis to cure; care cascade) to eradicate HCV at population level
- Primary care-based HCV treatment can help overcome access barriers

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CONTACT INFORMATION

Amber Slevin, PharmD, BCACP, CTTS

Clinical Pharmacist & Assistant Professor of Practice

Family HealthCare & North Dakota State University School of Pharmacy

Fargo, ND

Phone: 701-271-6363

Email: amber.slevin@ndsu.edu